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improvement wherein the blood sample is a thawed cryopreserved unit in accordance with claim 35.

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REMARKS

Claims 30-39, presented hereby in place of claims 19-25 and 27-29, are pending.

Claims 30-39 represent subject matter of claims 19-25 and 27-29, respectively, revised to more clearly define the invention, as explained, below.

Applicants wish to thank Examiner Jana A. Hines for the courteous consideration rendered applicants' representative during an interview at the PTO on 17 January 2002. The interview involved discussion of specific amendments to claims 19, 25, 27, 28, and 29 for addressing §112, ¶2, rejections of record, and a discussion of the rejections of record under 35 USC 103(a).

Reconsideration of the rejections of record under 35 USC 112, ¶2, is requested in view of the changes to claim language found in the present claims.

According to the statements of rejection, the rejected "claims lack a correlation step. The correlation step should correlate detecting the immunofunctional, toxic, and/or modulatory reaction and determining the reaction of blood" and "it is unclear how to determine what reactions are not encompassed by the term blood reaction." Claims 30 and 36-39, presented hereby, revise rejected claims 19, 25, 27, 28, and 29, respectively, so that such a correlation step is recited and the term "blood reaction" is modified to clarify the "reactions . . . encompassed by the term.

More precisely, claim 30 (text in *italics* representing language added to effect the correlation and clarify "blood reaction") recites in pertinent part

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- contacting the material or object with a sample of whole blood from human or animal donors for a period in a manner required to produce *an immunofunctional, toxic, and/or modulatory reaction*, . . . and
- detecting and/or measuring the immunofunctional, toxic, and/or modulatory reaction . . . *to determine the reaction of blood.*

Each of claims 36, 37, 38, and 39 (text in italics representing language added to effect the correlation and clarify "blood reaction") recites in pertinent part:

In a method for detecting and/or measuring an immunofunctional, toxic, or modulatory blood reaction against the material or object comprising . . . detecting and/or measuring the *immunofunctional, toxic, or modulatory* blood reaction by a biological, physical, chemical, or physicochemical method . . . .

The aforesaid changes represent the specific changes presented to the Examiner during the interview, as mentioned above.

Thus, in view of the aforesaid changes to the rejected claims represented by the present claims, Applicants submit that the rejections of record under 35 USC 112, ¶2, are overcome.

Reconsideration is requested with respect to the rejection of record under 35 USC 103(a) based on Wendell in view of Boyse'681.

According to the statement of rejection, the motivation to combine the references as alleged is "as a mere alternative and functionally equivalent blood sample, frozen/non-frozen." The allegation is insufficient to show the motivation required to establish obviousness under §103.

The fact that all elements of a claimed invention are known does not, by itself, make the combination obvious. *Ex parte Clapp*, 227 USPQ 972 (BPA&I 1985). It is legally erroneous to reach a conclusion of obviousness under §103 solely on the basis that the claimed invention

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represent a "combination which only unites old elements with no change in their functions." *Pentec, Inc. v. Graphic Controls Corp.*, 227 USPQ 766, 771 (Fed. Cir. 1985). As stated by the United States Court of Appeals for the Federal Circuit ("Federal Circuit") in the decision *In re Rouffet*, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998),

invention itself is the process of combining prior art in a nonobvious manner [*citations, omitted*]. Therefore, even when the level of skill is high, the . . . [USPTO] must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination.

As the Federal Circuit has also held,

. . . it is impermissible to use the claims as a frame and the prior art references as a mosaic to piece together a facsimile of the claimed invention.

*Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988),

and:

It is insufficient that the prior art disclosed the components of the patented device, either separately or used in other combinations; there must be some teaching, suggestion, or incentive to make the combination made by the inventor.

*Northern Telecom, Inc. v. Datapoint Corporation*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990), *cert. denied*, 498 U.S. 920 (1990).

The mere fact that it is possible to find two isolated disclosures which might be combined in such a way as to produce a new compound does not necessarily render such production obvious unless the art also contains something to suggest the desirability of the proposed combination.

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*In re Bergel*, 130 USPQ 206, 208 (CCPA 1961). It must be remembered that "invention itself is the process of combining prior art in a nonobvious manner [*citations omitted*]." *In re Rouffet*, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998).

In the instant situation, the alleged motivation merely begs the question, i.e., there is no mention of where in the prior art the alleged motivation can be found.

Moreover, an allegation of functional equivalence does not establish the requisite motivation to demonstrate obviousness under §103(a). Section does not require inventions to an improvement over, or more complex than, the prior art in order to be nonobvious. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 7 USPQ2d 1222, 1225 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 956 (1988). "Nothing in the patent statute requires that an invention be superior to the prior art to be patentable." *Ryco Inc. v. Ag-Bag Corp.*, 8 USPQ2d 1323, 1328 (Fed. Cir. 1988). "An invention need not *operate* differently than the prior art to be patentable, but need only *be* different." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

Accordingly, it is submitted that the rejection under §103 based on Wendell in view of Boyse'681 cannot be maintained.

Reconsideration is requested with respect to the rejection of record under 35 USC 103(a) based on Wendell in view of Dinarello and Boyse'553.

The statement of rejection discounts applicants arguments against the rejection as "attacking references individually," relying on *In re Keller*, 208 USPQ 871 (CCPA 1981), and *In re Merck &*

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Co., 231 USPQ 375 (Fed. Cir. 1986). Reliance on the cited decisions is misplaced, since they are not on point.

In the decisions cited in the statement of rejection, the applicant had argued against the rejection as if it were based on each of the cited references, separately. That is, the applicant had merely pointed out the claim limitations missing from one of the cited references, then another. That is not the fact pattern presented here.

In the present situation, applicants pointed out defects in a reference, not merely as limitations missing from the rejected claims, but to show how the references could not be combined in the manner alleged in the statement of rejection. It is well settled that "individual defects of the reference . . . can defeat the rejection" based on a combination of references. *Ryko Manufacturing Co. v. NuStar, Inc.*, 21 USPQ2d 1053 (Fed. Cir. 1991). *In re Lyons*, 150 USPQ 741, 746 (CCPA 1966). Accordingly, applicants submit that their arguments of record overcome the rejection under §103(a) based on Wendell in view of Dinarello and Boyse'553.

Attached, hereto, is the requested drawing correction for review and approval by the examiner.

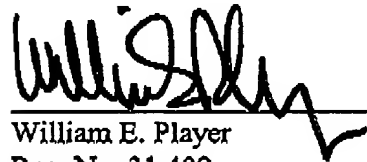
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Favorable action is requested.

Respectfully submitted,

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